Attachment 22

Altria
Altria Client Services

Paige C. Magness
Senior Vice President
Regulatory Affairs

November 27, 2019

Via Electronic Submission

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2019-N-3065 (84 Fed. Reg. 60,966, November 12, 2019) – Comments on "Tobacco Products; Required Warnings for Cigarette Packages and Advertisements; Additional Materials; Reopening of the Comment Period"

Altria Client Services LLC ("ALCS"), on behalf of Philip Morris USA Inc. ("PM USA") and Sherman Group Holdings, LLC and its subsidiaries ("Nat Sherman")[1] submits these comments to the U.S. Food and Drug Administration ("FDA" or the "Agency") in response to *Tobacco Products; Required Warnings for Cigarette Packages and Advertisements; Additional Materials; Reopening of the Comment Period.* The comments that follow supplement our comments previously submitted in response to this docket.[2]

While we support regulations that are science-and-evidence based and are implemented in a manner consistent with law, this rulemaking suffers from legal and scientific shortcomings that are not cured by the recent publication of additional materials. In the comments that follow, we demonstrate that: first, the newly disclosed qualitative study reports do not support subjecting HeatSticks® to the graphic health warning requirements in FDA's Proposed Rule on Required Warnings for Cigarette Packages and Advertising (the "Proposed Rule");[3] second, the qualitative study reports do not resolve Administrative Procedure Act ("APA") violations and undermine FDA's assertion that the proposed graphic health warnings would effectively improve public

---

[1] PM USA and Nat Sherman are wholly-owned subsidiaries of Altria Group, Inc. ("Altria"). PM USA manufactures cigarettes and is licensed to sell and distribute IQOS® and HeatSticks® in the United States and Nat Sherman sells premium cigars and manufactures and sells super premium cigarettes. ALCS provides certain services, including regulatory affairs, to the Altria family of companies. "We" and "our" are used throughout to refer to PM USA and Nat Sherman.

[2] ALCS comments to Docket No. FDA-2019-N-3065 (84 Fed. Reg. 42,754, August 16, 2019) –"Tobacco Products; Required Warnings for Cigarette Packages and Advertisements Proposed Rule," *available at* https://www.regulations.gov/document?D=FDA-2019-N-3065-0450 ("Oct. 15, 2019 ALCS Comments").

[3] Tobacco Products; Required Warnings for Cigarette Packages and Advertisements, 84 Fed. Reg. 42,754 (August 16, 2019).

Altria Client Services LLC
2325 Bells Road
Richmond, Virginia 23234
(804) 335-2353
Paige.C.Magness@altria.com

III. THE QUALITATIVE STUDY REPORTS DO NOT RESOLVE APA VIOLATIONS AND UNDERMINE FDA'S ASSERTION THAT THE PROPOSED GRAPHIC HEALTH WARNINGS WILL EFFECTIVELY IMPROVE PUBLIC UNDERSTANDING OF THE HEALTH CONSEQUENCES OF SMOKING

Neither FDA's decision to disclose the qualitative research study reports, nor the information that they contain, cure the APA failings we described in our prior comments. First, FDA has not released other critical data underlying the Proposed Rule, defying legal requirements and making it impossible for interested parties to adequately evaluate the proposed text or graphics, the process for developing them, or FDA's claims about its research results and decisions. Second, the study reports do not resolve APA violations. Third, the newly disclosed materials cast yet further doubt on FDA's claim that the proposed graphic health warnings would promote greater public understanding of the negative health consequences of cigarette smoking.

A. FDA has not released other critical data underlying the Proposed Rule

Despite the release of four additional documents, FDA still has not provided enough information to allow interested parties to meaningfully evaluate the textual and graphic contents of the warnings, the process by which FDA developed them, and FDA's characterization of its findings and decisions. FDA should release the final datasets from its quantitative studies so that parties can replicate and verify statistical analyses and examine data quality. FDA should also provide the transcripts from its qualitative studies[16] so that parties can evaluate completeness and potential bias – including whether statements by study participants that the authors chose to include in the study reports accurately reflect the totality of the evidence obtained. FDA's failure to provide this information violates both the Family Smoking Prevention and Tobacco Control Act ("TCA") and the APA, as discussed in our prior comments, and precludes commenters from adequately testing whether FDA's rulemaking rests on sound science.[17]

B. The qualitative study reports do not resolve APA violations

The APA requires FDA to support its conclusions with substantial scientific evidence and to connect its proposed actions to evidence in the record.[18] As explained in our previous comments, FDA's interpretation of the scientific evidence suffers from many explanatory and evidentiary gaps that, if not addressed, would render any final rule invalid under the APA.[19]

The new qualitative study reports do not resolve those issues. To the contrary, these documents reinforce previously identified problems and raise additional concerns about the soundness of FDA's approach. Despite the release of additional documents, the record for this rulemaking does not contain enough evidence to sustain – and FDA still has not adequately explained – foundational decisions such as why FDA highlighted certain diseases over others, why it selected the graphics and text/graphic pairings it did, or how and why it determined that the chosen warnings are comprehensible. Facts and findings in these documents are often difficult to

---

[16] *See* Sept. 5, 2019 Request for Extension; *See* Oct. 15, 2019 ALCS Comments at 27-28; *See* Nov. 18, 2019 Request for Extension.
[17] *See* Oct. 15, 2019 ALCS Comments at 27-33.
[18] *Dickinson v. Zurko*, 527 U.S. 150, 164 (1999); *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962).
[19] Oct. 15, 2019 ALCS Comments at 26-45.